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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/316,226	05/21/99	LENTZ	M LEN-101-CIP

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EXAMINER

BIANCO, P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED:

09/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/316,226

Applicant
Lentz, M. Rigdon

Examiner
Patricia Blanco

Group Art Unit
3762



☒ Responsive to communication(s) filed on Jul 13, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-32 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 1-4 and 11-21 is/are allowed.

☒ Claim(s) 5-10, 22, 23, 25, 26, and 29-32 is/are rejected.

☒ Claim(s) 24, 27, and 28 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-29 have been considered but are moot in view of the new ground(s) of rejection.

Also, please note that the Declaration, filed with the response/amendment filed on 7/13/00, has not been considered but has been placed in the file. The Declaration was not signed by the author.

Information Disclosure Statement

The foreign patents cited by Applicant in the supplemental IDS (filed 2/7/00) have not been considered but have been placed in the file. The references are in German, no translations were provided, and therefore it is not clear as to what relevance, if any, they have to the claimed invention in the present application.

Claim Objections

Claim 5 is objected to because of the following informalities: At the end of line 2 in the claim "weigh tof" is recited. It appears to be a typographical error and should perhaps be - weight of-. Correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment to claim 5 renders it, and its dependents 6, 30 and 31, confusing to the Examiner. Previously the claim was dependent on claim 1, which required removing components from the blood, and then further required treating the tissue with an agent. Now, amended claim 5 recites treating the patient by removing components from the blood "in combination with an agent" selected from a grouping of various agents. Is this an error due to the claim amendment and Applicant still desires the limitation of a combination of removing components from blood with treatment of the tissue with an agent? Is this withdrawal of blood components including the listed "agent" grouping that is to be withdrawn? The examiner's interpretation of the claim is to read the limitations as being a combination of removing components from blood with treatment of the tissue with an agent. Correction of the claim language or an explanation is required.

Claims 7-9 recite the limitation "the soluble cytokine receptor molecules" in the claims. There is insufficient antecedent basis for this limitation in the claim.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 22, 23, 29, 30, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (4,708,713) in view of D'Amato (5,712,291).

Lentz discloses a method and system for inducing an immune response against tumors wherein an ultrafilter having a pore size of 0.003-0.007 microns removes components in the blood having a molecular weight of 200,000 Daltons or less (page 2, lines 8-33). It is further taught that a membrane having a pore size of less than 0.03 microns can separate blood components of a molecular weight less than 30,000 Daltons. Thus, a filter having pore size greater than 0.03 and less than 0.07 microns would be effective in removing components having a molecular weight of about 100,000 Daltons. One of ordinary skill in the art would have the skill to determine which pore size would be appropriate for the desired components to be successfully removed. The system also has a syringe pump for adding anticoagulant to the various parts of the device to prevent clotting during use. The system also has means for adding other necessary or desired components back to the blood. A pump adds nutrients or another necessary component to the blood from a holding chamber (col. 3, line 61-col. 4, line 32). With respect to claims 22, 23, 29 and 32 including the parts of the device in a kit form, it was widely

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practiced to make kits of all the parts of a system. Thus, it would have been obvious at the time of the invention for one of skill in the art to make a kit of the Lentz and D'Amato system.

Lentz does not disclose further treatment of the tissue with an agent is an anti-angiogenic compound, more specifically is thalidomide.

D'Amato teaches of treating a tissue, which may be a tumor, with an angiogenic agent, more specifically thalidomide. At the time of the invention, it was routine in the art to use angiogenic substances in treatment of cancer, specifically with tumors, to cut off or starve the tumor of blood supply and stop tumor proliferation. Therefore, modification of the Lentz system to add such an agent to the blood, and subsequently to the tumor, would ensure the tumor would have less blood supply and therefore aid in shrinking.

Claims 6, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz and D'Amato as applied to claims 5, 22, 23, 29, 30, 31 and 32 above, and further in view of Isner et al. (5,980,887).

Lentz and D'Amato DIFFER from the claims since they do not teach that the agent used for treatment be selected from the group erythropoietin, M-CSF and GM-CSF.

Isner teaches of administering agents such as erythropoietin, M-CSF and GM-CSF to a patient. At the time of the invention, it was routine in the art to use angiogenic substances in treatment of cancer or arthritis. Use of such agents in the system and method of Lentz and

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D'Amato would regulate, by enhancement or reduction, the angiogenesis necessary based on their disease.

Allowable Subject Matter

Claims 1-4 and 11-21 are allowed over the prior art.

Claims 24, 27 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 7-10 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Okarma et al. and Nakatani et al. disclose removal of blood components using filters and adsorbent columns, however, do not teach of the components as claimed by Applicant which are the cytokine receptors.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Patricia Bianco whose telephone number is (703) 305-1482 and fax number is (703) 306-4520. The Examiner can normally be reached on Monday through Thursday, and on alternate Fridays, from 6:30 AM until 6:00 PM at the above number.

pmb

September 23, 2000

Patricia Bianco

Angela D. Sykes

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